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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 1 recites a device comprising at least 16.5 μg of a latex-labeled specific binding reagent. This limitation is not supported by the specification as originally filed.

Applicant asserts that page 10 of the specification teaches that 2% w/v latex results in a deposition of about 22 micrograms, thus the 1.5% w/v of latex taught at page 14 will result in 16.5 micrograms because 1.5% is $\frac{3}{4}$ of 2% and $\frac{3}{4}$ of 22 is 16.5.

This is not persuasive. This calculation requires that the latex be from the same mixture which is clearly not the case in this instance. There appears to be no basis for this calculation. If one follows this logic, pages 13 and 14 discloses that 7.6 microgram is in a 0.5% w/v, and the object is to determine if increasing the amount of control latex deposited on the device would decrease the control signal development time, 1.5% of 7.6 microgram would result in 22.8 microgram. Thus, the specification as originally filed does not provide support for the invention as claimed.

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Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2, 5, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 5 do not further limit claim 1 from which they depend. Claim 2 recites an analyte which is not part of the device of claim 1.

Claim 5 recites an intended use of the device of claim 1 and is not further limiting.

Withdrawn Rejections

5. The rejection of claims 1, 3, 6, 9, 10, 11, 12 and 14 under 35 USC 102(e) as being anticipated by Mendel-Hartvig is withdrawn in view of the amendment to the claims. However, it is noted that the claim amendments are not supported by the specification as originally filed, therefore, cancellation of the new matter will result in the possible reinstatement of the art rejection.

6. The rejection of claims 1-6 and 9-14 under 35 USC 102(b) as being anticipated by May et al (US 5,602,040) is withdrawn in view of the amendments to the claims. However, it is noted that the claim amendments are not supported by the specification as originally filed, therefore, cancellation of the new matter will result in the possible reinstatement of the art rejection

7. The rejection of claims 7 and 8 under 35 USC 102(e) as anticipated by or in the alternative, under 35 USC 103(a) as obvious over Mendel-Hartvig is withdrawn in view of the amendments to the claims. However, it is noted that the claim amendments are not supported by the

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specification as originally filed, therefore, cancellation of the new matter will result in the possible reinstatement of the art rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
June 8, 2009